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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,260	03/26/2001	Nicholas J. Schork	G-085US04CON	9223
23557 7590 06/26/2008 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950				
EXAMINER LIN, JERRY				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/818,260

Applicant(s)

SCHORK ET AL.

Examiner

JERRY LIN

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 7, 40, 41 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7, 40, 41 and 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date 4/2/08
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' arguments and amendments, filed March 17, 2008, have been fully considered and they are deemed to be persuasive in-part. However, in light of newly discovered art, the following rejections are deemed necessary. These rejections constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1, 4, 7, 40, 41, and 46-50 are under examination.

Information Disclosure Statement

The reference by Jeffreys on the IDS filed April 2, 2008 has been lined through because it was previously considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claims 4, 46, and 47 are drawn to product. However, the last step of these claims includes the active process steps of executing and outputting. A product

claim that includes process steps is indefinite. For purposes of this office action, these process steps will be interpreted as intended use.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 4, 46, and 47 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Instant claims 4, 46, and 47 are drawn to a product that embodies a process involving the judicial exception of a computational algorithm. Claims drawn to a judicial exception is non-statutory unless the claims include a practical application of that judicial exception as evidenced by a physical transformation of the claimed invention, or if the claimed invention produces a useful, tangible and concrete final result. In the instant claims, there is no physical transformation by the claimed invention, thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result. See MPEP 2106.

The instant claims do not produce a useful, concrete, tangible final result. A tangible requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. The instant claims are drawn to a system with instructions to determine the statistical significance of a difference between haplotype frequency profiles. The system does not include any instructions to communicate the final results to the outside world. Thus the instant claims do not

require that a result must be produced. Since there is no final result in the embodied judicial exception, the instant claims do not include a useful, concrete, and tangible final result. This rejection could be overcome by amendment of the claims to identify/recite a concrete result and to recite that the result is outputted to a display or to a user or outputted in a user readable format. However, applicant is reminded that any amendment must be fully supported and enabled by the originally filed disclosure.

Response to arguments

5. Applicants have responded to this rejection by amending the claims to include the step of outputting the results obtained by execution of instructions to a printer or display. However, as stated above, this step is interpreted as an intended use of the computer. Thus, the process embodied by the instructions on the system does not have a useful, concrete, and tangible result.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4, 7, 40, 41, and 46 - 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanton, Jr. (US 2002/0039990) in view of Kidd et al. (Human Genetics (1998) Volume 103, pages 211-227) and in view of Jeffreys (US 5,811,235).

Stanton, Jr. teaches a method of determining the statistical significance of a difference between haplotype frequency profiles of at least two groups of individual which includes determining the combined likelihood that the two groups of individuals are derived from the same distribution of haplotypes, determining the sum of the separate likelihoods that each of the two groups of individuals are derived from the same distribution of haplotypes, and determining the difference of the sum and combined likelihood (page 65, paragraph 0825).

Stanton, Jr. does not teach obtaining the haplotypes of individuals for each group by genotyping the same chromosome, randomly permuting the haplotypes between groups to determine the probability that the groups do not come from the same distribution of haplotypes, or calculating all possible single-haplotype chi-square tests. Nor does Stanton teach using a binary code to identify the haplotypes of all individuals.

Kidd et al. teach a method of determining the haplotype frequencies of a population which include obtaining haplotypes for all individuals in each of two groups of individuals by genotyping the same gene which is located on the same chromosomal

segment (Page 212, right column, bottom - page 213); randomly permuting the haplotypes between groups to determine the probability that the groups do not come from the same distribution of haplotypes (page 213, right column; page 216); assessing the statistical significance of individual haplotypes using a P-excess value (page 224). Regarding claim 40 in particular, Kidd et al. teach calculating all possible single-haplotype chi-square tests (page 224).

Jefferys teaches a method of characterizing genomic DNA which includes providing binary codes for an allele or a haplotype (column 2, lines 38- column 3, line 7); and using that code to generate an array (column 16, lines 38-43, Fig. 1A).

Stanton teaches implementing his methods using computer programs and computer storage devices including outputting results to a storage or display (Stanton, page 65, paragraph 0825; page 45, paragraph 0512).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the references of Stanton, Kidd et al., and Jefferys to gain the benefit of creating a computer system for comparing frequencies and establishing the correlations between a phenotype and genotype. Kidd et al.'s methods provide the advantage of determining the statistical significance of a correlation between a phenotype and genotype (Kidd et al., page 213) which would supports Stanton's stated goal of identifying variances within genes (Stanton, page 1, paragraph 0006). In addition, Jefferys states that a system of generating a large number of unambiguous DNA phenotypes in a database would be advantageous for comparing frequencies and would require binary coding (Jefferys, column 2, line 38-65). Thus, one of ordinary skill

in the art would have been motivated to add Jefferys's method to binary coding of alleles to the above references (Stanton, page 65, paragraph 0825). Furthermore, since all the methods are computational, one of ordinary skill in the art would have a reasonable expectation of success in combining the above reference.

Withdrawn Rejections

8. Applicant's arguments and amendments, filed March 17, 2008, with respect to the rejection of claims 1, 7, 40, 41, and 48-50 under 35 U.S.C. §101 as non-statutory, have been fully considered and are persuasive. The instant claims have been amended to include a tangible final result or a tangible computer readable medium which is sufficient to overcome the rejection under 35 U.S.C. §101. This rejection has been withdrawn.

Conclusion

No claim allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on 7:00-5:30pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/
Examiner, Art Unit 1631
6/20/2008